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# The primary entries in the Reportable Food Registry

#### JEL codes: C38, I10, K32, L66, P46

**Keywords:** food safety, United States, Food and Drug Administration, Reportable Food Registry **Summary.** Presented the assumptions of the Reportable Food Registry (RFR), which was established in the United States by the Food and Drug Administration (FDA). Examined in which way the most frequently reported hazards were related to commodities, using the cluster analysis (method of joining). Presented these relationships in tree diagrams. Indicated the disadvantages of the RFR, but also some possibilities of comparison of the RFR entries and the European Rapid Alert System for Food and Feed (RASFF) notifications.

#### Introduction

The Reportable Food Registry (RFR) launched in 2009 as the electronic portal established in the United States by the Food and Drug Administration (FDA) based on the FDA Amendments Act of 2007, in order to better protect public health. This portal was replaced in 2010 by the Safety Reporting Portal, concerning also the RFR. To the RFR industry must and public health officials may report (USFDA, 2011) within 24 hours (Batt, 2016; Dzanis, 2008) when they have information about a reportable food, i.e. an article of food for which is a reasonable probability that the use of, or exposure to, this food will cause serious adverse health consequences or death to humans or animals (USFDA, 2011). The primary reports (entries) in the RFR concern initial submissions related to food or feed (including food ingredients) (USFDA, 2011).

In table 1 primary RFR entries (reported from September of previous year to September of next year within the five-year period) by commodity and year were presented (USFDA, 2016). Some commodities names were shortened (full original names were given below table 1). The entries for particular commodity didn't occur in each year. Moreover, some of commodities have been added or removed in particular annual reports (USFDA, 2011, 2012, 2013, 2014, 2016).

Commodity	Year 1	Year 2	Year 3	Year 4	Year 5	Total
	(2009–2010)	(2010–2011)	(2011–2012)	(2012–2013)	(2013–2014)	
Acid Canned Food	2	2	2	1	0	7
Animal Food/Feed	28	19	19	30	18	114
Bakery	16	20	18	22	23	99
Beverages	3	2	1	1	4	11
Breakfast Cereals	2	0	3	1	2	8
Chocolate	8	7	12	11	16	54
Dairy	18	16	20	10	24	88
Dressings	6	8	5	6	6	31
Egg	2	2	2	0	0	6
Frozen Foods	9	11	3	10	12	45
Fruits/Vegetables	12	9	5	3	5	34
Game Meats	1	0	0	0	0	1
Meal Replacement	6	2	5	4	2	19
Multiple Products	4	1	2	2	2	11
Nuts/Seeds	16	16	13	15	10	70
Oil/Margarine	1	0	0	0	0	1
Pasta	0	1	2	1	2	6
Prepared Foods	11	14	9	12	17	63
Produce – Fresh Cut	13	9	23	13	11	69
Produce – Raw	14	27	33	10	14	98
Seafood	17	18	17	19	7	78
Snack Foods	7	9	7	10	4	37
Soup	4	0	6	2	2	14
Spices/Seasonings	17	25	8	12	12	74
Stabilizers	8	5	5	6	6	30
Sweeteners	0	0	0	0	1	1
Grains/Flours	4	2	4	1	1	12
Total	229	225	224	202	201	1081

Table 1. Primary RFR entries by commodity and year

Notes: Acid... Canned Food – Acidified/Low Acid Canned Food; Chocolate... – Chocolate/Confections/Candy, Dressings... – Dressings/Sauces/Gravies, Fruits/Vegetables – Fruit and Vegetable Products, Meal Replacement... – Meal Replacement/Nutritional Food and Beverages, Nuts/Seeds – Nuts/Nut Products/Seed Products, Produce – Raw... – Produce – Raw Agricultural Commodities, Spices/Seasonings – Spices and Seasonings, Stabilizers... – Stabilizers/Emulsifiers/ Flavors/Colors/Texture Enhancers, Grains/Flours – Whole and Milled Grains and Flours. Source: USFDA (2016).

The number of the RFR entries in subsequent years decreased. Should be also noted, however, that in each annual report commodities were distributed across following hazards: Drug Contamination, E. coli, Excessive Urea, Foreign Object, Lead, Listeria monocytogenes, Nutrient Imbalance, Other, Salmonella, Undeclared Allergens, Undeclared Sulfites, Uneviscerated Fish (not all hazards were presented in each annual report). In the report for 2013–2014 didn't already occur hazards: Foreign Object, Other and Uneviscerated Fish (the number of entries in the previous reports was small) and a new hazard: Lead was added. The greatest number of entries was related to three haz-

ards: Undeclared Allergens in Bakery, Chocolate/Confections/Candy, Dairy, Frozen Foods, Prepared Foods, Snack Foods, Salmonella in Animal Food/Feed, Nuts/Nut Products/Seed Products, Produce - Raw Agricultural Commodities, Spices and Seasonings and also Listeria monocytogenes in Dairy, Prepared Foods, Produce – Fresh Cut, Produce – Raw Agricultural Commodities and Seafood (USFDA, 2011, 2012, 2013, 2014, 2016).

Therefore, the goal of the study was to examine in which way hazards within the primary entries in the RFR were related to commodities.

### 1. Data and methods

The data originated from the annual RFR reports published by the FDA and concerned 1081 primary entries from 2009–2010 to 2013–20014. In each of the five report the data were given in the table, where in rows the commodities (as in table 1) and in columns hazards were presented (USFDA, 2011, 2012, 2013, 2014, 2016). The data, separately for each year, were collected in Excel and then transferred to Statistica 12.

The cluster analysis with the following settings: joining (tree clustering), linkage rule: complete linkage, distance measure: Euclidean distance was used. The hazards were adopted as variables and aggregation was carried out according to rows (commodities). However, if the number of entries for a given commodity was 0, it was removed before analysis. The results of cluster analysis were presented graphically in tree diagrams. The circles (concerning clusters) and hazard names (below the particular cluster, also single clusters) were added in Paint.

## 2. Results and discussion

In figures 1–5 the tree diagrams for subsequent examined years were presented. The changes in arrangement of clusters in the subsequent years could resulted not only from different number of primary entries, but also a different number of commodity and hazard categories. However, in a bottom part of each diagram in particular clusters the commodities with the greatest number of primary entries were mostly focused.



Figure 1. Tree diagram for year 1 (2009-2010)

Source: own study based on calculations in Statistica 12.



Figure 2. Tree diagram for year 2 (2010–2011)

Source: own study based on calculations in Statistica 12.



Figure 3. Tree diagram for year 3 (2011–2012)

Source: own study based on calculations in Statistica 12.



Figure 4. Tree diagram for year 4 (2012–2013)

Source: own study based on calculations in Statistica 12.



Figure 5. Tree diagram for year 5 (2013–2014) Source: own study based on calculations in Statistica 12.

The linkage distance between particular commodities in a bottom part was longer than in a upper part of diagrams. The arrangement of clusters in this part of diagrams was related mostly to hazards: Undeclared Allergens, Salmonella and Listeria monocytogenes (see also Introduction). The commodities with similar number of primary entries within given hazard (see USFDA, 2011, 2012, 2013, 2014, 2016) were directly related. However, in a greater clusters occurred additionally also commodities with entries within given hazard or these commodities were related indirectly (through other clusters) if the number of entries was clearly higher.

So, the clusters with the longest linkage distances were concentrated around three above mentioned hazards. The entries related to Undeclared Allergens have been reported only in processed food and Salmonella and Listeria monocytogenes mostly in primary food (less in processed food). Gendel (2014) noted that the FDA monitors food allergens through the analysis of the consumer complaints, recalls and entries to the RFR. Van Doren et al. (2013a, 2013b) drew attention to RFR primary entries related to Salmonella in spices and seasonings. The RFR recalls concerning Salmonella in nuts and spices also were noticed by Keller (2014). Zach et al. (2012) pointed even that recalling of peanut products was a cause of establishing of the RFR.

Batt (2016) stated that the RFR with the roll out of Food Safety Modernization Act will be used to enhance the public awareness of potential safety challenges. However, Millard et al. (2015) noted that the RFR does not alter product traceability in a fundamental way.

### Conclusions

The primary entries of the RFR related to Undeclared Allergens were reported only in processed food (mainly within following commodities: Bakery, Chocolate/Confections/Candy, Dairy, Frozen Foods, Prepared Foods and Snack Foods). Whereas, the bacteria: Salmonella and Listeria monocytogenes were mostly reported in primary food (less in processed food). Salmonella was reported in Animal Food/Feed, Nuts/Nut Products/Seed Products, Produce – Raw Agricultural Commodities and Spices and Seasonings. Listeria monocytogenes was reported in Dairy, Prepared Foods, Produce – Fresh Cut, Produce – Raw Agricultural Commodities and Seafood.

The results of the cluster analysis indicated that the primary entries of the RFR were concentrated around these three hazards in the bottom parts of tree diagrams with the longest linkage distances between commodities.

The annual reports of the RFR so far published concerned only 5 years (from 2009–2010 to 2013–2014). They didn't cover the full calendar year but periods from September to September. The commodities or hazards in particular reports were withdrawn or added. The RFR does not have the open access. These disadvantages of the RFR make it difficult or even impossible to track trends over time and comparison of changes in the number of entries.

However, the further development of the RFR would allow to make comparisons in the number the RFR entries and notifications in the European Rapid Alert System for Food and Feed (RASFF). It would be necessary to take into account e.g.: omitting some products, combining certain categories of products and hazards, the size of the American and European population.

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#### POWIADOMIENIA PIERWOTNE W REPORTABLE FOOD REGISTRY

**Słowa kluczowe:** bezpieczeństwo żywności, Stany Zjednoczone, Agencja ds. Żywności i Leków, Reportable Food Registry

**Streszczenie.** Zaprezentowano założenia *Reportable Food Registry* (RFR), który został ustanowiony w Stanach Zjednoczonych przez Agencję ds. Żywności i Leków (FDA). Zbadano w jaki sposób najczęściej zgłaszane zagrożenia są związane z produktami, stosując analizę skupień (metodę aglomeracji). Relacje te zaprezentowano na diagramach drzewa. Wskazano na wady RFR, ale także na możliwości porównania zgłoszeń w RFR ze zgłoszeniami w europejskim Systemie Wczesnego Ostrzegania o Niebezpiecznej Żywności i Paszach (RASFF).

Tłumaczenie Marcin Pigłowski

# Cytowanie

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